

DEC 9 2005

HITACHI
Basic Information**4.2.1 Manufacturers Name (Ultrasound Scanner):** Hitachi Medical Corporation**Address:** Hitachi Kamakurabashi Bldg., 1-1-14
Uchi-kanda, Chiyoda-ku
Tokyo 101-0047 Japan**Corresponding Official:** Doug Thistlethwaite
Manager, Regulatory Affairs**Address:** Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087**Telephone:** (330) 425-1313**4.2.2 Initial Distributor (Ultrasound Scanner) :** Hitachi Medical Systems America, Inc.**Address:** 1959 Summit Commerce Park
Twinsburg, Ohio 44087**Telephone:** (330) 425-1313**4.2.3 Device Name:** EUB-6500 Diagnostic Ultrasound Scanner**4.2.4 Common Name:** Diagnostic Ultrasound Unit**4.2.5 Classification****Regulatory Class:** Class II**Review Category:** Tier II

	<u>FR Number</u>	<u>Product Codes</u>
<u>Ultrasonic Pulsed Echo and Pulsed Doppler Imaging System</u>	892.1550	90-IYN
<u>Diagnostic Ultrasound Transducer</u>	892.1570	90-ITX

4.2.6 Establishment Registration Number: Hitachi Medical Corp. (Japan) 8030405
Hitachi Medical Systems America, Inc. (USA) 1528028**4.2.7 514 Performance Standards:** None**4.2.8 Special Controls:** Special Report – to be filed at a later date**4.2.9 Prescription Status:** Prescription Device**4.2.10 Manufacturing Location (Ultrasound Scanner):** Hitachi Medical Corporation - Kashiwa Works
2-1 Shintoyofuta
Kashiwa-shi, Chiba-ken
277-0804 Japan**4.2.11 Sterilization Site(s):** N/A Device is not shipped as sterile.**4.2.12 Reason for Submission:** Modification to existing product**4.2.13 TRACK Followed for Submission:** Track 3



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Hitachi Medical Corporation
% Mr. Doug Thistlewaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K053258

Trade Name: EUB-6500 Diagnostic Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulatory Name: Ultrasonic pulsed echo imaging system
Regulatory Number: 21 CFR 892.1570
Regulatory Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: November 14, 2005
Received: November 22, 2005

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the EUB-6500 Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

EUP-B514
EUP-C312T

EUP-C314G
EUP-C511

EUP-C516
EUP-C524
EUP-C532
EUP-CC531
EUP-CV524
EUP-F334
EUP-L34T
EUP-L52
EUP-L53
EUP-L53L

EUP-L65
EUP-O53T
EUP-R54A-19
EUP-R54A-33
EUP-R54AW-19
EUP-R54AW-33
EUP-S50
EUP-S50A
EUP-S52
Fujinon SP711

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

System:

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

EUB-6500

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)	P	P	P		P	P	P
	Laparoscopic	P	P	P		P	P	P
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)	Pg	Pg	Pg		Pg	Pg	Pg
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

P = Previously Cleared, K013723

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign Off)

Division of Reproductive, Abdominal, ~~ENT~~,
and Radiological Devices

510(k) Number:

K053258

Prescription Use 

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-B514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

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Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K053258

Prescription Use ☒

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-C312T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

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Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal, ~~ENT,~~
and Radiological Devices

510(k) Number: K053258

Prescription Use

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-C314G

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal, ~~ENT~~,
and Radiological Devices

510(k) Number:

K053258

Prescription Use ☒

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-C511

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	E	E	E		E	E	E
	Cardiac Pediatric	E	E	E		E	E	E
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K053258

Prescription Use _____

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-C516

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

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Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon
 (Division Sgn-Off)

Division of Reproductive, Abdominal, ~~ENT~~,
 and Radiological Devices

510(k) Number:

K053258

Inspector: Joe

System: EUB-6500
Transducer: EUP-C524

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	E	E	E		E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	E	E	E		E	E	E
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel							
	Other (spec.)							

****Amplitude Doppler, Harmonic Imaging and 3D Imaging.**

Subscript "h": Includes imaging for guidance of transrectal biopsy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K053258

[illegible]

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-C532

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)	Eb	Eb	Eb		Eb	Eb	Eb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic	E	E	E		E	E	E
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number:

K053258

Inspector: SL2 ✓

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-CC531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Ee	Ee	Ee		Ee	Ee	Ee
	Trans-vaginal	Ef	Ef	Ef		Ef	Ef	Ef
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

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Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-CV524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Spec.)	N	N	N	N	N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication.

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT,
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510(k) Number: K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-F334

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Eb	Eb	Eb		Eb	Eb	Eb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
	Neonatal Cephalic	E	E	E		E	E	E
	Adult Cephalic							
	Trans-rectal	E	E	E		E	E	E
	Trans-vaginal	E	E	E		E	E	E
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.


Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K053258

DATE: 11/11/04

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-L34T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number:

K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-L52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & II)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K053258



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500

Transducer: EUP-L53

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number:

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-L53L

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,
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510(k) Number:

K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-L65

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number:

K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-O53T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Eb	Eb	Eb		Eb	Eb	Eb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-R54A-19

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E	E	E
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,
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510(k) Number:

K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-R54A-33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E	E	E
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: KA53258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-R54AW-19

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E	E	E
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ~~ENT,~~
 and Radiological Devices

510(k) Number: K053258



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-R54AW-33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E	E	E
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number:

K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: EUP-S50

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E	E	E	E	E
	Abdominal	Ea	Ea	Ea	Ea	Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E	E	E	E	E
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	E	E	E	E	E	E	E
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	E	E	E	E	E	E	E
	Cardiac Pediatric	E	E	E	E	E	E	E
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E	E	E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

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Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: R053258



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-S50A

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E	E	E	E	E
	Abdominal	E	E	E	E	E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E	E	E	E	E
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	E	E	E	E	E	E	E
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	E	E	E	E	E	E	E
	Cardiac Pediatric	E	E	E	E	E	E	E
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E	E	E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

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Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Prosdrom
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Division of Reproductive, Abdominal, ~~ENT,~~
and Radiological Devices

510(k) Number: K05-3258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
Transducer: EUP-S52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E	E	E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec	Ec	Ec	Ec	Ec
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	E	E	E	E	E	E	E
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

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Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


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Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K053258

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6500
 Transducer: Fujinon SP711

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal	E						
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

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